JUL 3 0 2003

# Appendix F

## 510(k) Summary

| | |
|---|---|
| **Submitter:** | SIGNUS Medical LLC<br>6713 Lakeway Drive<br>Chanhassen, MN 55317 |
| **Contact Person:** | Mr. Thomas Hoghaug<br>Managing Director<br>Phone: (952) 974-9456<br>Fax: (952) 975-0465 |
| **Date Prepared:** | June 3, 2003 |
| **Trade Name:** | PEEK Tetris™ |
| **Classification Name and Number:** | 21 CFR 888.3060 |
| **Product Code:** | MQP |
| **Predicate Device Name and 510(k) Number** | Titanium Tetris™<br>K022793 |
| **Device Description:** | DEVICE DESCRIPTION<br>The PEEK Tetris™ Spinal Implant is a hollow, rectangular frame with lateral fenestrations. The upper and lower aspects of the implants are open and the walls feature spikes, which assist in the positive anchorage and seating of the implants between the superior and inferior vertebral bodies. The frame is forged from PEEK which is radiolucent and incorporates Titanium alloy marker pins so the device can be located within the body.<br><br>The PEEK Tetris™ Spinal Implant is available in a variety of sizes and a wedge shaped option. This enables the surgeon to choose the size suited to the individual pathology and anatomical condition. |
| **Intended Use:** | The PEEK Tetris™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). |

| | |
|---|---|
| | The PEEK TETRIS™ Spinal Implant is intended for use with supplemental internal fixation.<br><br>The supplemental internal fixation systems that may be used with the PEEK Tetris™ Spinal Implant include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile). |
| **Statement of Technological Comparison** | Representative samples of the device underwent testing to demonstrate comparable functional and performance characteristics to the predicate device.<br><br>The patient contact materials of the PEEK Tetris™ are processed in the same manner and are identical to those used in other legally marketed predicate devices from SIGNUS that have undergone appropriate biocompatibility testing. Therefore biocompatibility testing of the PEEK Tetris™ has been fulfilled by analogy to those devices. |
| **Conclusion:** | The PEEK Tetris™ is substantially equivalent to the Titanium Tetris™ . This conclusion is based upon the fact that this device is substantially equivalent to the predicate device in terms of functional design, indications for use, principles of operation and test performance characteristics. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2003

Mr. Thomas Hoghaug
Managing Director
SIGNUS Medical LLC
6713 Lakeway Drive
Chanhassen, MN 55317

Re: K031757
Trade Name: PEEK Tetris™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: July 7, 2003
Received: July 8, 2003

Dear Mr. Hoghaug:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

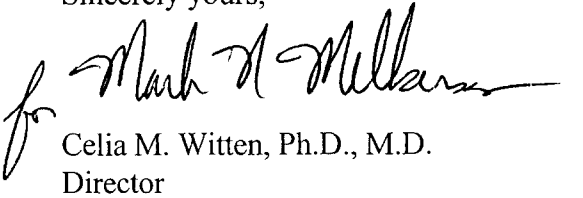
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031757



# Appendix B

## Indications for Use Statement

**510(k) Number** (if known) TBD

**Device Name** PEEK Tetris™

**Indications for Use**

The PEEK Tetris™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5).

The PEEK Tetris™ Spinal Implant is intended for use with supplemental internal fixation.

The supplemental internal fixation systems that may be used with the PEEK Tetris™ Spinal Implant include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

for Mark A Milkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031757